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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	8

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/801,115	Applicant(s) MA ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   A. Claims 1-16, drawn to an isolated polynucleotide, classified in class 536, subclass 23.1.

   B. Claims 17-22, drawn to an isolated polypeptide, classified in class 530, subclass 350.

   C. Claim 23, drawn to an antibody of the polypeptide, classified in class 530, subclass 387.1.

   D. Claim 24, drawn to a compound which inhibits activation of the polypeptide, classified in class 514, subclass 2.

   E. Claim 25, drawn to a method of using the CKLF1 polypeptide in the preparation of immunological adjuvants, classified in class 435, subclass 4.

   F. Claim 26, drawn to a method for the treatment of a patient having need of the CKLF polypeptide comprising administering the polypeptide, classified in class 514, subclass 12.

   G. Claims 26-27, drawn to a method for the treatment of a patient having need of the CKLF polypeptide by providing to the patient DNA encoding said polypeptide, classified in class 514, subclass 44.

   H. Claims 28-33, drawn to a method of diagnosing a disease or susceptibility to a disease comprising determining a mutation in the polynucleotide, classified in class 435, subclass 6.

   I. Claim 29, drawn to a diagnostic method comprising analyzing for the presence of the polypeptide, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

   a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups A-D

are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group B can be prepared by processes which are materially different from recombinant DNA expression of Group A, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group A can be used other than to make the protein of Group B, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group B can be used in materially different methods other than to make the antibody of Group C, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group C can be used to obtain the DNA of Group A, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The compound of Group D may be structurally different than the products of Groups A, B, and C and can be used in methods other than to inhibit the activation of the protein of Group B, such as cell culture assays or immunoassays.

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions E-I are different methods because they require different ingredients, process steps, and endpoints. Groups E-I are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention E requires search and consideration of utilizing the CKLF1 polypeptide to prepare immunological adjuvants to improve the curative effect of a DNA vaccine or DNA drug, which is not required by the other inventions. Invention F requires search and consideration of efficacy of treatment by administration of the CKLF1 polypeptide, which is not required by the other inventions. Invention G requires search and consideration of efficacy of therapy of administration of DNA

encoding the CKLF1 polypeptide, which is not required by the other inventions. Invention H requires search and consideration of determining a mutation in a polynucleotide to diagnose a disease or disease susceptibility, which is not required by the other inventions. Invention I requires search and consideration of assaying for the presence of a polypeptide, which is not required by the other inventions.

c. Inventions A and F/G are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used to a generate a polypeptide or to create transgenic animals.

d. Inventions B and E/F/I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used as an antigen for the production of antibodies.

e. Inventions A and E/F/I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups A and E/F/I are unrelated product and methods, wherein each is not required, one for another. For example, the composition of Invention A cannot be used together with the claimed methods of Inventions E/F/I because these inventions do not recite the use or production of the polynucleotide of Invention A.

f. Inventions B and G/H are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups B and G/H are unrelated product and methods, wherein each is not required, one for another. For example, the composition of Invention B cannot be used together with the claimed methods of Inventions G/H because these inventions do not recite the use or production of the polypeptide of Invention B.

g. Inventions C/D and E-I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups C/D and E-I are unrelated product and methods, wherein each is not required, one for another. For example, the compositions of Invention C and D cannot be used together with the claimed methods of Inventions E-I because these inventions do not recite the use or production of the antibody or compound of Inventions C and D.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and divergent subject matter, restriction for examination purposes as indicated is proper.

2. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Groups 1-4. The inventions as they pertain to each of SEQ ID NOs:
1, 3, 5, or 7, classification dependent upon the nature of the inventions.

The inventions are distinct, each from the other because of the following reasons:

h. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs: 1, 3, 5, and 7 is a nucleic acid unique sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. The, the only common feature of the recited SEQ ID NOs: is a general secondary structure resemblance, which is not a basis upon which to base a search and examination of the claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements and divergent subject matter, restriction for examination purposes as indicated is proper.

3. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Groups 5-8. The inventions as they pertain to each of SEQ ID NOs: 2, 4, 6, or 8, classification dependent upon the nature of the inventions.

The inventions are distinct, each from the other because of the following reasons:

i. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs: 2, 4, 6, and 8 is a unique amino acid sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. The only common feature of the recited SEQ ID NOs: is a general secondary structure

resemblance, which is not a basis upon which to base a search and examination of the claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements and divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of diagnosing a disease or a susceptibility to a disease wherein the disease comprises:

aa. inflammations
bb. degenerative diseases
cc. primary tumors
dd. hematopoietic disorders

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-27 and 29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In order to be fully responsive, Applicant must select one from Groups A-I, one from 1-4, and one from 5-8. Applicant is advised that groups A-I, 1-4, and 5-8 are not species election requirements; rather, each of A-I, 1-4, and 5-8 is a restriction requirement.

Furthermore, if Applicant elects Group VIII, one species from the disorder group must also be chosen to be considered fully responsive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
March 22, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER